National Environmental Laboratory **Accreditation** Conference

Proficiency Testing Program

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2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For the period beginning with adoption of these standards by NELAC and ending September 30, 1998, all NELAP-approved accrediting authorities shall accept data from proficiency testing programs that meet the requirements of current EPA or state regulations and guidance. The intent of these interim standards is to continue the status quo until remaining EPA and other stakeholder issues can be addressed. This should not be construed as NELAC approval or disapproval of any particular PT provider.

Accrediting authorities may rely on the current laboratory performance evaluation studies conducted by EPA. These include: the Water Supply (WS) Study, conducted twice annually; the Water Pollution (WP) study, conducted twice annually; and the Discharge Monitoring Report Quality Assurance (DMRQA), conducted once annually. Alternatively, accrediting authorities may rely on other sources for performance evaluation studies (such as their own state-operated programs or programs supported by commercial vendors), provided that these programs meet current EPA regulatory requirements.

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC Proficiency Testing (PT) Program. In addition to complying with the requirements of this Chapter, any person, private party or government entity seeking to participate as a PT Provider in the NELAC program shall also comply with the requirements of the applicable Appendices A (PT Provider Approval Criteria), B (PT Sample Design and Acceptance Guidelines), C (Proficiency Testing Acceptance Criteria and Proficiency Testing Pass/Fail Criteria) and D (Proficiency Testing Oversight Body). The criteria set forth in this standard are considered to be default requirements, and shall be used in the absence of specific program criteria. If they conflict with any documented EPA program criteria, the program criteria shall have precedence.

Proficiency Testing (PT) is defined for the purpose of this Chapter as a means of evaluating a laboratory’s performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. PT is not the sole criterion for determining accreditation status. Additional essential

elements of the overall NELAC accreditation process, including the laboratory audit, are discussed in other chapters of the NELAC standards. The PT program is intended to cover all types of federal and state environmental analyses. However, the body of the PT standard applies primarily to chemistry. *Appendices (yet to be developed) will describe necessary variations as applied to radiochemistry, biology, and microbiology.*

The major components of the NELAC PT Program include:

a) multiple PT Providers who shall meet stringent criteria to become Approved by the Proficiency Testing Oversight Body (PTOB), as described in Section 2.3 and Appendix A;

b) specific requirements for the design of PT samples and studies, to ensure that all samples provide a consistent, fair and known challenge to laboratories seeking NELAC Accreditation, as described in Section 2.3 and Appendix B;

c) specifically defined pass/fail criteria for evaluating PT sample results, as described in Section 2.3 and Appendix C;

d) initial approval and ongoing oversight of PT Providers by the Proficiency Testing Oversight Body (PTOB), Section 2.3 and Appendix D;

e) specific requirements for laboratories participating in PTOB Approved PT Programs, as described in Sections 2.5, 2.6, and 2.7; and

f) oversight of all PT Program activities by the PTOB, as described in Section 2.2.1.

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:

a) the production and supply of test samples that are procedure-sensitive; that is, the samples challenge the critical components of each analytical procedure, ranging from initial sample preparation to final data analysis;

b) the production and supply of test samples that are as similar to real-world samples as is reasonably possible. It is further expected that the PT samples will be representative of environmental regulatory programs, agencies, and communities;

c) a program which is affordable by all participants;

d) the yielding of PT data that are technically defensible on the basis of the type and quality of the samples provided;

e) the preparation of samples such that the identification and quantitation of analytes in the samples poses equivalent difficulty and challenge regardless of the manner in which the samples are designed and manufactured by the PT Providers, i.e. samples prepared for analysis by a Drinking Water or Wastewater method would pose equal challenge whether prepared as whole volume or concentrated ampules.

2.1.2 Goals

The PT program incorporates several practical goals, which include:

a) the generation of data at a quality level required by environmental and regulatory programs;

b) the generation of data that are, at a minimum, comparable in quality to that of currently certified and/ or accredited laboratories; and

c) the improvement of the overall performance of laboratories over time.

2.1.3 PT fields of testing

The PT program is organized by PT fields of testing. Laboratories may choose to participate in one or more PT fields of testing, or portions thereof. The following elements collectively define PT fields of testing:

a) Regulatory or environmental program

b) Matrix

c) Analyte

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the Proficiency Testing Oversight Body (PTOB), the PT Providers, the laboratories, and the Accrediting Authorities (AA). The lines of interaction among these groups are shown in Figure 1.

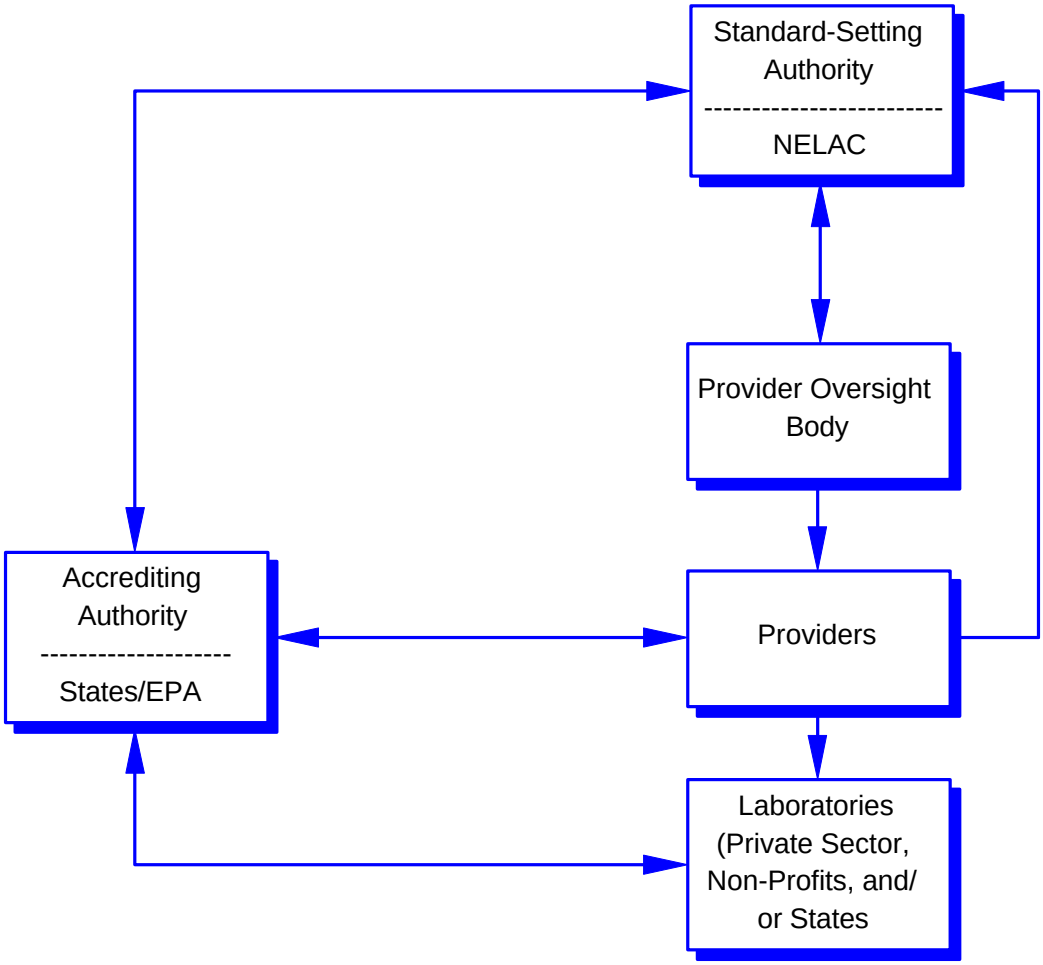

Figure 2-1. NELAP Proficiency Testing

2.2.1 NELAC and NELAP

NELAP is the Standards Setting Authority (SSA) which is responsible for administering the NELAC PT program. EPA and the states established NELAC to develop the written standards by which the PT program will operate and to keep these standards current relative to the needs of regulatory

and environmental laboratory programs. The NELAC standing Proficiency Testing Committee determines PT fields of testing, sample parameters, sample concentration ranges, frequency of testing, and PT sample acceptance criteria. NELAC meets annually to evaluate the PT programs, collect input from the participants, their associated groups, and the regulated community, and revise the standards as needed. NELAC reviews and approves the PT sample acceptance criteria as described in Appendix C.

2.2.2 PT Study Providers

The providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective Accrediting Authorities, the PTOB, and NELAP. The PT Provider shall meet the requirements of Appendix A, manufacture samples that meet the requirements of Appendix B, and score sample results in accordance with the requirements of Appendix C.

2.2.3 Proficiency Testing Oversight Body (PTOB)

The Proficiency Testing Oversight Body (PTOB) shall establish and implement a program to accredit PT study suppliers and to monitor accredited suppliers to ensure that their studies and practices meet all applicable standards. The PTOB shall meet the requirements of Appendix D.

2.2.4 Laboratories

Laboratories that seek to become accredited by NELAP shall perform analyses of PT samples as required by this chapter. PT samples shall be obtained from NELAP Approved PT Providers. The laboratory shall obtain PT samples from any NELAP Approved PT Provider. The results of the analyses shall be submitted to the Provider for scoring.

2.2.5 Accrediting Authorities (AA)

The States or the EPA Regions which hold primary Accrediting Authority are the Accrediting Authorities for those laboratories located within their respective boundaries. The accrediting authorities shall make all decisions regarding a laboratory’s accreditation status. They are responsible for taking action to make these determinations.

2.3 REQUIREMENTS FOR PT PROVIDERS

This section and associated Appendix A describe the criteria that all PT providers shall meet in order to be approved by the PTOB as PT Providers. The PTOB shall grant approval to PT providers on a field-of-testing basis, as described in Section 2.1.3.

2.3.1 On-Site Inspection of PT Providers

The PTOB shall conduct an on-site inspection of any organization seeking to participate as a PT Provider in the NELAC Program, as described in Appendix D. The PTOB shall determine whether the Provider meets the applicable requirements described in this chapter and Appendices A, B, and C. Approval of a PT Provider shall be the responsibility of the PTOB. The PTOB shall conduct ongoing oversight of the PT Providers as necessary to ensure conformance with all applicable standards.

2.3.2 Sample Requirements and Design

This Section and associated Appendix B describe PT sample design and acceptance criteria. The matrices of all PT samples shall to the extent possible, resemble the matrices for which the laboratory seeks accreditation. Samples may not be reused.

2.3.2.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the target concentration of each analyte in each lot is unique. The required group of analytes in each sample covering each field of testing shall be determined by NELAC and shall be evaluated and updated annually, as necessary. For a given field of testing, it is not necessary that every analyte be present in every study. Within each study, a certain minimum number of analytes shall be present. The group of analytes included shall change over time so that all analytes are eventually included over a series of sequential studies.

2.3.2.2 Provider Sample Testing

The PT Provider shall design, manufacture, and test the samples for homogeneity, stability, and verification of target values as required by Appendix B. This testing shall

verify that the quality of all samples is acceptable for use in each field of testing PT study.

2.3.3 PT Study Data Analysis

This Section and associated Appendix C describe the criteria to be used by PT Providers when scoring and evaluating NELAC PT sample results.

2.3.3.1 Data Set Size Requirements

The PT Provider shall have enough participants to ensure that at least 20 valid data points are obtained for each analyte in each study. However, NELAP may waive this requirement for analytes that are analyzed infrequently by the laboratory community.

2.3.3.2 Data Acceptance Criteria

PT Providers shall use the data acceptance criteria described in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance will be judged fairly and consistently.

2.3.4 Generation of Study Reports

Each PT study provider shall demonstrate that it can receive and evaluate the data and issue a report within 21 calendar days of the close of each study.

2.3.5 Provider Conflict of Interest

Each PT study provider shall certify that it is free of any organizational conflict of interest. A PT sample producer shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each provider shall demonstrate that its security procedures are adequate to maintain confidentiality and security of all target values through the closing date of each study. All records shall be retained for a period of five years or as required by the appropriate regulatory program.

2.3.6 Disapproval of PT Study Providers

A PT Provider shall be disapproved if documented deviations from the standard identified by the AA, the PTOB, or participating laboratories are not resolved within 30

calendar days after the provider is notified in writing of the problem (Refer to Appendix A).

2.3.7 PTOB Listing of PT Providers

The PTOB shall maintain a list of Approved PT Providers. The PTOB shall evaluate, update, and publish this list at intervals not to exceed six months. On this same interval, The PTOB shall also publish the list of PT fields of testing necessary to satisfy the PT requirements.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, each laboratory shall participate in a PT study provided by a NELAP Approved PT Provider. Laboratories must request accreditation for a field of testing, as described in Section 2.1.4 of this Chapter. Each laboratory shall participate in at least two PT studies per year. The PT Provider shall design studies that require the analysis of one test sample for each field of testing. Section 2.5 describes the time period in which a laboratory must analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this Chapter.

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the accrediting authority which field of testing, that it chooses to complete to meet PT requirements. For those tests for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Chapter 5 of the NELAC standards.

2.4.3 Reporting Results

Laboratories seeking accreditation may select any provider from the list of PTOB Approved PT study providers. The laboratories shall bear the cost of any PT study subscription. Each laboratory shall authorize the PT study provider to report its results and pass/fail status directly

to the appropriate accrediting authority, NELAP and the PTOB, in addition to the laboratory.

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

A laboratory must participate in two PTOB-approved single-blind, single- concentration PT studies per year for each field of testing for which it seeks or wants to maintain accreditation. The samples shall be analyzed and the results returned to the PT study provider no later than 30 calendar days from the date of sample receipt. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples to the extent possible. The laboratory shall utilize the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for real environmental samples.

2.5.1 Restrictions on Exchanging Information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

a) A laboratory shall not send any PT sample or a portion of a PT sample to another laboratory for any analysis for which it seeks accreditation;

b) A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation;

c) A laboratory shall not allow management or staff to communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample; and

d) Laboratory management and staff shall not attempt to obtain the target value of any PT sample from the provider.

2.5.2 Maintenance of Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the assessors of the primary accrediting authority during on-site audits of the laboratory.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

Program specific criteria apply where available, but in the absence of specific criteria established by the appropriate EPA program offices the criteria presented in this section and associated Appendix C are considered to be NELAC defaults that would apply.

2.6.1 Scoring of Laboratory PT Sample Results

PT study providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria as described in Appendix C. NELAC shall provide (and update on an annual basis) the data acceptance criteria that all PT study providers shall use for all PT study data. Each result will be scored on an acceptable/not acceptable basis. The PT study provider will provide the participant laboratories, the accrediting authority, the PTOB, and NELAP a report showing at least the target value, the acceptance range, and the acceptable/not acceptable status for each analyte for each laboratory participant. The providers shall not disclose specific laboratory results or evaluations to any other parties not described in this section.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

The criteria presented in this section are considered to be NELAC defaults that would apply in the absence of specific criteria established by the appropriate EPA program offices. The various EPA program offices may choose to establish their own program-specific criteria.

2.7.1 Result Categories

The criteria described in this section apply individually to each field of testing, as defined by the laboratory seeking accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the accrediting authority will consider PT results along with the other elements of the NELAC standards when determining a laboratory's accreditation status. The accrediting authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT result categories: "acceptable" and "not acceptable."

2.7.2 Initial and Continuing Accreditation

A laboratory which seeks accreditation shall successfully complete two PT studies for each requested field of testing within the most recent three rounds attempted. Successful performance is described in Appendix C. Once a laboratory has been granted accreditation status, it must continue to complete PT studies and maintain a history of at least two successful studies out of the most recent three. For either initial or continuing accreditation, completion dates of successive proficiency testing rounds for a given field of study must be at least semiannual (i.e., not more than six months apart) but must be at least 30 days apart (i.e., participation in a second study or a remedial study may not occur within 30 days of the first or failed study). Failure to meet the semiannual schedule is regarded as a failed study.

2.7.3 Supplemental Studies

A laboratory may elect to conduct PT studies more frequently than required by the semiannual schedule as set by the primary accrediting authority. This may be desirable, for example, when a laboratory first applies for accreditation or when a laboratory fails a study and wishes to quickly re-establish its history of successful performance. These additional studies are not distinguished from the routinely scheduled studies; that is, they are counted and scored the same way. Periodic PT studies will occur at fixed times per year (schedule to be determined). Initial and remedial samples can be obtained at other times.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records both the investigation and the action taken. If a laboratory fails two out of the three most recent studies for a given field of testing, its performance is considered unacceptable under the NELAC PT standard for that field.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT performance results to the accrediting authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study, as described above, the accrediting authority shall take action within 60 days to determine the capability of the laboratory to meet accreditation requirements. The accrediting authority shall review the accreditation status of all methods related to the analyte(s) in the failed study, and not just the method by which the failed PT was analyzed.

APPENDIX A

PT PROVIDER APPROVAL CRITERIA

A.0.0 SCOPE

This Appendix describes the responsibilities and requirements a Proficiency Testing (PT) Provider shall meet in order to be a Proficiency Testing Oversight Body (PTOB) Approved PT Provider. In order for a PT Provider to participate in the NELAC PT Program, a Provider must be approved by the PTOB. The criteria provided below are designated to ensure the integrity and technical excellence of the NELAC PT Program while allowing all qualified Providers to participate in the program.

A.1.0 APPROVAL PROCESS

The process for approval of a PT Provider includes an annual on-site inspection by the PTOB to ensure that the technical criteria of this appendix are being met. At the discretion of the PTOB, the PT Provider may be requested to confirm their ability to perform analyses within the required limits through participation in a proficiency testing program operated by the PTOB, or through the analysis of unknown samples provided by the PTOB. Providers are also required to submit the results of PT programs operated for NELAC to the PTOB for review and evaluation. The PT Provider agrees to accept the findings and decisions of the PTOB as final.

A.2.0 QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider must meet the requirements of both ISO 9001 for the design, production, testing, and distribution of performance evaluation samples and the requirements of ISO Guide 34 Quality System Guidelines for the Production of Reference Materials. The design and operation of the PT Provider’s proficiency testing program must meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons. The testing facilities used to support the verification, homogeneity, and stability testing required in Appendix B of this document must meet the requirements of Chapter 5, Quality Systems, of the NELAC standards for the quality of testing facilities. The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider’s quality system by an ANSI accredited registrar. However, an annual on-site inspection by the PTOB demonstrating continuing performance is required.

A.3.0 PROVIDER FACILITIES AND PERSONNEL

Each Provider is required to have systems in place to produce, test, distribute, and provide data analysis and reporting functions for any series of samples for which they are requesting approval. Similarly, the Provider shall have in place sufficient technical staff, instrumentation, and computer capabilities as may be required by the PTOB to support the production, distribution, analysis, data collection, data analysis, and reporting functions of the samples. No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study.

A.4.0 SAMPLE DESIGN REVIEW

The PT Provider must demonstrate to the PTOB, by the submission of appropriate data, that the sample design for which the PT Provider is seeking approval will permit participating laboratories to generate results that fall within the sample acceptance ranges established by NELAC or the PTOB.

A.4.1 RELEASE OF INFORMATION

In support of the above requirement, the PTOB agrees to treat all sample design information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such design information shall not be released by the PTOB without the prior written consent of the PT Provider.

A.5.0 PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

PT Providers seeking approval shall document to the satisfaction of the PTOB that they do not have a conflict-of-interest with any laboratory seeking, or having, NELAC accreditation. PT Providers shall notify the PTOB of any actual or potential organizational conflicts of interest, including but not limited to:

a) Any financial interest in a laboratory seeking, or having, NELAC accreditation;

b) The sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAC accreditation.

The PT Provider is also required to inform all internal and contract personnel who perform work on NELAC PT samples of their obligation to report personal and organizational conflicts of interest to the PTOB. The Provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of NELAC PT programs. If an actual or potential organizational conflict of interest is identified during performance of work in support of NELAC PT programs, the PT Provider shall immediately make a full disclosure to the PTOB. The disclosure shall include a description of action which the Provider has taken or proposes to take, after consultation with the PTOB, to avoid, mitigate or neutralize the actual or potential conflict of interest. The PTOB may reevaluate a PT Provider's Approval status as a result of unresolved conflict of interest situations. Any conflict of interest disputes between the PT Provider and the PTOB may be appealed to NELAP for a final determination.

A.5.1 BAN ON DISTRIBUTION OF SAMPLES

Furthermore, PT Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers further agree not to sell, distribute, or provide samples of identical design and concentration to those samples which it is currently using in a NELAC study.

A.6.0 CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB that is has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs is not compromised. PT Providers shall not release the Target Value of any sample currently being used in a NELAC PT study. The PT Provider also agrees that the acceptance ranges provided to them by either NELAC, or the PTOB, are the proprietary information of NELAC or the PTOB and shall not be disclosed by the PT Provider without the written approval of the PTOB.

A.7.0 DATA REVIEW AND EVALUATION

The NELAP Approved PTOB will review the data from every PT Provider study to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB will also evaluate the performance of the PT Providers by monitoring and reporting to both and the Providers the pass/fail rates of all Providers on all samples tested. The PTOB is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8.0 COMPLAINTS & CORRECTIVE ACTION

Written complaints received by the PT Provider regarding their performance in the NELAP PT program must be submitted to the PTOB within seven days from receipt of the complaint by the PT Provider. The PT Provider shall resolve the complaint to the satisfaction of the PTOB within 30 days from the date received by the PTOB. The PTOB is the sole judge of the adequacy of the corrective action taken by the PT Provider. It is the responsibility of the PTOB to provide NELAP with an annual summary of all PT Provider complaints received during the prior year.

A.9.0 LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of this appendix or those of Appendix B, may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based upon review of PT study data by the PTOB as required in Appendix A Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections A2 through A6, on a continuous basis may lose their approval as a PTOB Approved PT Provider for all samples.

A.9.1 PERIODIC REVIEW OF PT PROVIDERS

The PTOB may at any time, review the performance of any approved PT Provider against the terms and conditions of both Appendix A and Appendix B. Based upon this review, the PTOB may determine that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

A.9.2 REVOCATION OF APPROVAL

The PTOB may take any of the following actions in response to its determination that a PT Provider's approval status should change:

a) If the PT Provider fails to meet the requirements of Appendix B for a particular sample set or series of sample sets, the PTOB may revoke approval of the PT Provider to provide these sample sets for the NELAC PT program. PT Providers may request reapproval for the sample sets by verifying to the PTOB that the problem has been corrected.

b) If the PT Provider fails to meet the requirements of Appendix A Section A2 or A3, the PTOB may revoke the PT Provider's approval to supply any samples under the NELAC PT program until such time that the PT Provider corrects the problem and the PTOB verifies through an on-site inspection that the corrective action has been effective.

c) If the PT Provider fails to meet the requirements of Appendix A, Sections A5 through A6, the PTOB may revoke the PT Provider's approval to supply any samples under the NELAC PT program. In this case, the PT Provider may not reapply for reapproval for a period of three years from the date of revocation of approval.

APPENDIX B

PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES

B.0.0 INTRODUCTION

An integral element of the NELAC PT Program Standards is the assurance of PT samples which are of high quality, well documented, homogeneous, and stable. In order to meet the goals of NELAC, the PT samples used in the program must also provide all laboratories with samples which offer a consistent challenge. All PT samples must meet all applicable specifications by EPA and/or NELAC.

B.1.0 VERIFICATION OF TARGET VALUE

All PT samples used in the NELAC program must be analyzed by the PT provider prior to shipment to the laboratories to ensure suitability for use in the program. The Target Value of the sample will be used to establish acceptance criteria, and it must be verified by analysis. PT providers must verify the Target Value by direct analysis against NIST Standard Reference Materials, if a suitable NIST SRM is available for use. If a NIST SRM is not available then verification must be performed against an independently prepared calibration material. An independently prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.

B.1.1

The method used by the PT provider for verification analysis must have a relative standard deviation of not more than fifty percent of relative standard deviation predicted by the laboratory acceptance criteria being used by NELAC for each parameter. The relative standard deviation of the provider’s verification method will be established by a method validation study, and the suitability for use will be approved by the NELAP designated Proficiency Testing Oversight Body (PTOB).

B.1.2

Every parameter in all PT samples must be verified by analysis. The Target Value of the sample is verified if the Target Value of the sample falls within a 99% Confidence Interval calculated from the Mean and Standard Deviation of the data generated during the verification analysis.

B.2.0 HOMOGENEITY VERIFICATION

PT sample homogeneity is essential to ensuring that all laboratories are treated fairly. Therefore, the purpose of the homogeneity testing procedure is to ensure that within a 95% Confidence Limit that all samples distributed to the laboratories have the same Target Value for every parameter to be evaluated. Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.

B.2.1

The homogeneity of the samples must be established using a generally accepted procedure. The procedure selected by the PT provider must be capable of evaluating the relative consistency of each analyte across the production run, and must be performed on the final packaged samples. The procedure must establish within a 95% Confidence Limit that the Target Value is consistent across the production run. Samples or parameters which fail to pass the homogeneity testing criteria of the procedure used by the PT provider at the 95% Confidence Interval cannot be used in the NELAC PT program to evaluated laboratories.

B.2.2

A suitable homogeneity testing procedure will be capable of comparing the within sample to between sample standard deviation across the PT provider’s packaging run and will ensure comparability within a 95% Confidence Interval. Suitable homogeneity testing procedures are available in both ISO Guide 35 for the Certification of Reference Materials and in the REMCO/AOAC Harmonized Protocol for the Proficiency Testing of Analytical Laboratories. However, the homogeneity testing procedure used by the PT provider must be approved for use by the PTOB.

B.3.0 STABILITY TESTING

The samples used in the NELAC PT program must to verified as stable for the period of each study. Therefore, the stability of all samples, and parameters, must be established by the PT provider following the close of data submission from the laboratories. The samples are considered stable for the period of the study if the Mean analytical value as determined after the study for each

parameter falls within the 99% Confidence Interval calculated for the prior to shipment verification testing used to verify the Target Value. The testing procedure used for stability testing must be approved for use by the PTOB.

B.4.0 SAMPLE DESIGN APPROVAL

The sample design for each sample used in the NELAC PT program must be evaluated, and approved for use, by the PTOB prior to their use in the NELAC program. The criteria for design adequacy are that the sample will provide equivalent challenge to the laboratories as similar samples for the same parameters as other providers, and that the sample will exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.

B.4.1

The testing and verification protocol required to establish sample equivalency will be agreed to by both the PT provider and the PTOB on a case by case basis. It is the responsibility of the PT provider to demonstrate the adequacy of sample design to the satisfaction of the PTOB.

B.5.0 DATA REPORTING BY PT PROVIDERS

The results of sample Target Value verification, homogeneity, and stability testing must be available to the participating laboratories. All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis must be provided to any laboratory participating in the program upon request after the close of the study.

B.5.1

The data developed by the PT provider in support of verification, homogeneity, and stability testing will be supplied in summary format to the PTOB in an electronic format to be determined by the PTOB. Verification and homogeneity data must be supplied to the PTOB prior to sample distribution to the laboratories.

B.5.2

All data from the laboratories and the results of stability testing must be provided to the PTOB in an electronic format to be determined by the PTOB within thirty days of the close of the study.

APPENDIX C

PROFICIENCY TESTING ACCEPTANCE CRITERIA AND PROFICIENCY TESTING PASS/FAIL CRITERIA

C.0.0 PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the criteria to be used by any entity which seeks to participate as a Proficiency Test Provider in the NELAC Program for scoring the results obtained from the analyses of samples in any NELAC PT Study. Two distinct sets of scoring criteria are defined: 1) whether or not an individual analyte result is either "Acceptable" or "Not Acceptable" and 2) whether or not a laboratory's PT performance for a group of interdependent analytes can be evaluated as "Pass" or "Fail". The PT Providers shall submit all laboratories' performance rating(s) to the Accrediting Authority, as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory's NELAP accreditation status. PT acceptance limits and pass/fail criteria are established according to PT fields of testing, which are defined in Chapter 2 of the NELAC standards.

C.1.0 ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each individual analyte. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number of results that are determined to be acceptable.

C.1.1 ANALYTE ACCEPTANCE LIMIT CATEGORIES

Acceptance limits are separated into three categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 will be used in the determination of a laboratory's PT Field of Testing pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 will not be used as part of the PT Field of Testing pass/fail evaluation.

C.1.1.1 Analytes with EPA Promulgated Acceptance Limits

PT Providers shall utilize the proficiency test acceptance limits that have been promulgated in regulations or guidelines by EPA programs. The most recent EPA regulations and/or guidelines are incorporated into this Appendix by reference. EPA's promulgated proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:

- **Target ± fixed percentage.** Acceptance limits shall be set at plus and minus the published fixed percentage of the analyte's validated target value.

- **Mean ± 2 standard deviations.** For those analytes for which the PTOB has established linear regression equations relating target value to mean and target value to standard deviation, acceptance limits shall be set using said equations and the sample's validated target value. Linear regression equations may only be used for target values that fall within the range of target values used to establish said equations. In the event that there are no linear regression equations available for a given analyte, that analyte will be treated as described in Section C.1.1.3.

C.1.1.2 Analytes with acceptance limits derived from regression equations established by the PTOB and approved by the NELAC

When EPA Program regulation or guidance for establishing acceptance criteria are not available Proficiency Test providers shall set acceptance limits as follows. Regression equations that predict the mean and standard deviation for an analyte in a given range of concentrations in PT samples will be derived by the PTOB. Data from sources such as the EPA PE studies, interlaboratory results from professional organizations such as ASTM, other proficiency testing providers, commercial and non-profit organizations, will be used to establish the equations. All regression equations will be approved by the NELAC prior to use by a PTOB Approved PT provider. For these analytes, the PT Provider shall use the sample's validated target value and said equations to determine the mean and standard deviation. The regression equations shall be designed to be applicable across the NELAC designated PT concentration range.

C.1.1.3 Analytes without promulgated acceptance limits or EPA established regression equations, i.e., "Experimental Data"

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits will be established only after interlaboratory data has been collected for a minimum

of one year unless the PTOB determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". NELAC with the assistance of the Proficiency Testing Oversight Body, will derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory will receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.2.0 "ACCEPTABLE" PT RESULTS FOR CHEMICAL ANALYTES IN POTABLE WATER, NON-POTABLE WATER AND HAZARDOUS WASTE PT SAMPLES

A laboratory's PT analyte result is "Acceptable" when it falls within the EPA's promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample's validated target value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the 99% prediction interval based on the mean and standard deviation. A result is "Acceptable" when it falls within these derived acceptance limits.

C.3.0 "NOT ACCEPTABLE" PT RESULTS FOR POTABLE WATER, NON-POTABLE WATER AND HAZARDOUS WASTE PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) The result falls outside the EPA's promulgated acceptance limits (Section C.1.1.1) or outside the 99% prediction interval derived from PTOB established regression equations (Section C.1.1.2);

b) The lab reports a result for an analyte not present in the PT sample (i.e., a false positive);

c) The lab reports a result of "Not Detected", for an analyte present in the PT sample (i.e., a false negative);

NOTE: False positives and false negatives will only be scored "not acceptable" when an analyte has an EPA promulgated required detection limit (RDL). For example if a laboratory reports a result above the EPA

promulgated RDL for a given analyte that is not present in the PT sample, then the result will be classified as a false positive and scored as "not acceptable". Conversely, if a laboratory reports a result less then the RDL for an analyte present in the PT sample at a concentration within the NELAC approved PT concentration range, the result will be classified as a false negative and scored as "not acceptable".

d) The lab fails to submit its results to the PT Provider on or before the deadline for the PT study.

C.4.0 ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionally large failure rates or reporting anomalies to the Proficiency Testing Oversight Body. All proficiency test data are to be submitted to the PTOB in the format specified by the PTOB and shall be reviewed annually by the NELAC Standing Committee for Proficiency Testing in conjunction with the EPA for the purpose of revising existing and establishing new linear regression equations.

C.5.0 NELAC PT STUDY PASS/FAIL CRITERIA

NELAC PT samples are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections C.1 through C.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this Section. Pass/Fail criteria are used when groups of interdependent analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

C.5.1 INTERDEPENDENT ANALYTE PT SAMPLES

Interdependent analyte PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes. Examples of interdependent PT Samples are those used for the following series of analytes; volatiles, semivolatiles, pesticides, herbicides, etc..

C.5.2 NON-INTERDEPENDENT ANALYTE PT SAMPLES

Non-interdependent PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate an analyte or a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. Non-interdependent analyte PT samples may contain a single analyte, e.g., pH, BOD, TSS, etc., or may contain multiple analytes, e.g., metals, major ions, etc.

C.5.3 PROMULGATED EPA PASS/FAIL CRITERIA

In all cases, promulgated EPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), will be used as NELAC PT pass/fail criteria as applicable. The criteria described in the following Sections, 5.4 and 5.5, shall be used in the absence of promulgated EPA pass/fail guidelines.

C.5.4 PASS/FAIL CRITERIA FOR INTERDEPENDENT ANALYTE PT SAMPLES

Proficiency Testing pass/fail evaluations for Interdependent Analyte PT samples shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for 80% of the analytes in an Interdependent Analyte PT Sample. Greater than 20% "Not Acceptable" results will result in the laboratory receiving a score of "Fail" for that series of analytes.. For example, a laboratory must report all "Acceptable" results for an Interdependent Analyte PT Sample containing 1-4 analytes, may report no more then one "Not Acceptable" result for a Sample containing 5-9 analytes, two "Not Acceptable" results for a Sample containing 10-14 analytes, etc… A "Not Acceptable" result for the same analyte in two consecutive PT studies will also result in the laboratory receiving a score of "Fail" for that analyte.

C.5.5 PASS/FAIL CRITERIA FOR NON-INTERDEPENDENT ANALYTE PT SAMPLES

To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for all analytes in a Non-Interdependent Analyte PT Sample. One or more "Not Acceptable" results will result in the laboratory

receiving a score of “Fail” for that Field of Testing sample.

APPENDIX D

PROFICIENCY TESTING OVERSIGHT BODY

D.0.0 PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the qualifications, scope of responsibilities and requirements for the NELAC designated Proficiency Testing Oversight Body (PTOB) as defined in Section 2.2.3 of the NELAC document. In addition to complying with the requirements of this Appendix, the PTOB, for this oversight function, shall comply with the applicable requirements described in Chapter 2 and associated Appendices A (PT Provider Acceptance Criteria), B (PT Sample Design and Acceptance Guidelines), and C (Criteria for Setting PT Data Acceptance Limits).

D.1.0 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

The PTOB shall demonstrate to NELAP that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight. The PTOB shall meet the following general requirements:

a) The PTOB shall demonstrate the capability to manage and evaluate complex environmental reference materials in a variety of matrices;

b) The PTOB shall demonstrate expertise in statistical applications as related to large interlaboratory performance evaluation programs;

c) The PTOB shall demonstrate the capability to conduct on-site audits of PT Providers;

d) The PTOB shall demonstrate the capability to conduct technical reviews of Initial Applications;

e) The PTOB shall demonstrate a knowledge and understanding of the ISO guides 9001, 34, 43, and Chapter 2 of the NELAC standards including Appendices A, B, and C.

D.2.0 PTOB RESPONSIBILITIES REGARDING INITIAL ASSESSMENT OF PT PROVIDERS

The PTOB responsibilities are described in this section. The primary responsibility of the PTOB is the oversight and ongoing monitoring and evaluation of the PT Providers. The oversight activities of the PTOB shall be designed to ensure

that the PT Provider meets the requirements specified in Chapter 2 and Appendices A, B and C. All activities described herein shall be conducted by the PTOB.

D.2.1 DEVELOPMENT OF STANDARD OPERATING PROCEDURES AND FORMS

The PTOB shall develop the Standard Operating Procedures (SOPs) necessary to conduct the PT Provider evaluation process. These documents shall be based upon the requirements of Chapter 2 of the NELAC standards and the associated Appendices A, B, and C. NELAP has the authority to review and approve, as necessary, the SOPs developed by the PTOB.

D.2.1.1 SOP(s) for the Assessment Process

The PTOB shall develop and implement SOP(s) including but not limited to: the initial application submittal and review process, on site inspection, submittal of final reports to NELAP, the procedures for recommending that a PT Provider's approval be revoked, the procedures for appealing approval recommendations, and any other procedures deemed necessary by NELAC.

D.2.1.2 Initial Application

The PTOB shall develop the initial application process to be submitted by all PT Providers applying for approval as PT Providers of NELAC samples. The application shall include questions regarding the qualifications of the organization seeking approval. In addition to completing the initial application process, the PTOB shall require that the PT Provider submit copies of its current ISO 9001 registration certificate or any other documents which detail the quality systems required by the provisions of Chapter 2 and associated Appendices.

D.2.1.3 SOP(s) for On-Site Inspections and Checklist(s)

The PTOB shall develop a SOP for conducting consistent, effective, annual on-site inspections of PT Providers. The SOP shall include policies which describe the circumstances for conducting any additional inspections, and circumstances for determining whether on-site inspections will be announced or unannounced. The PTOB shall develop standard,

consistent checklist(s) to be used during any and all inspections of PT Providers.

D.2.2 Initial Application Review and On-site Inspections

The PTOB shall follow the procedures described in this section for the review of applications and on-site inspections of any candidate PT Provider.

a) The PTOB shall review the initial application documents, described in D.2.1.2, for compliance with the PT Provider qualifications described in Appendix A and other applicable documents.

b) The PTOB shall review the sample designs used by the PT Provider for compliance with Appendix B and other applicable documents.

c) The PTOB shall review the PT analyte and sample scoring procedures used by the PT Provider for compliance with Appendix C and other applicable documents.

d) No later than ninety (90) days after the review of the Initial Application and associated documents, the PTOB shall conduct an on-site inspection of the PT Provider. The PT Provider shall be provided with checklist(s) to be used during the inspection as part of the initial application process. The inspection may be conducted more than 90 days after reviewing the initial application only if unforeseen circumstances beyond the control of the PTOB, prevent an inspection from being conducted within this time period. The inspection shall be conducted following the SOP(s) and documented on the checklist(s) described in Section D.2.1.3.

e) Following the inspection, the PTOB shall conduct an exit meeting with the PT Provider, which shall include discussion of deficiencies and discrepancies found; however, the PTOB may further revise the findings after the closing of the exit meeting, if necessary.

   The inspection shall include, at a minimum:

   1) Review of the quality system for adherence to the requirements of Appendices A, B and C;

2) Review of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples;

3) Review of the sample manufacturing and verification procedures to ensure that the requirements of Appendices A and B are met;

4) Review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of sample values; and

5) Review of data reporting systems to ensure that the requirements of Appendix C are met within the time periods specified in Chapter 2.

f) The PTOB shall send a draft report to the PT Provider no later than fourteen (14) days after the completion date of the inspection. The PTOB shall allow the PT Provider seven (7) days to review and comment on the draft if the PT Provider finds any discrepancies and determines that revisions are necessary. The PTOB shall then submit a final inspection report to the PT Provider no later than thirty-five (35) days after the completion of the on-site inspection. The final report may only contain discrepancies and findings identified during the on site inspection or discussed during the exit briefing.

g) The PTOB shall allow the Provider no less than thirty (30) days to submit their response to the report. In order for the Provider's response to be considered acceptable, the PTOB shall require that it include a description of corrective actions necessary to meet the criteria of Chapter 2, and Appendices A, B, and C.

D.2.3 Final Report Submittal NELAP and the PT Provider

No later than ninety (90) days after the completion date of inspection, the PTOB shall submit to NELAP and to the Provider a final report that includes the PTOB's final inspection report, the Provider's response to the inspection report, and the review of the initial application with associated documents. The report shall also include the PTOB's determination of whether the PT Provider is approved to provide NELAC samples.

D.3.0 PTOB Responsibilities Regarding Approval of PT Providers

The PTOB shall utilize the appropriate final report and associated documents submitted by the PT Provider to grant or deny approval to that Provider.

D.4.0 PTOB RESPONSIBILITIES FOR ONGOING OVERSIGHT OF PT PROVIDERS

The PTOB shall conduct ongoing oversight of all approved PT Providers. The oversight shall include at a minimum:

a) the use of referee laboratories to verify the concentrations of analytes in randomly selected PT Provider samples;

b) the statistical monitoring of PT Provider's study data to detect occurrences which indicate samples of unacceptable quality, i.e., failure rates that exceed expected norms, analyte standard deviations that exceed expected intervals, and analyte mean recoveries which are significantly above or below historical trends. The ongoing monitoring criteria to be used by the PTOB will be developed by NELAC.

c) biannual on site audits of the PT provider review and monitoring of critical operational parameters of the PT provider, i.e., change in senior management, sale of the company.

d) on site inspections of the PT provider for cause.

Based upon the results of its ongoing oversight, the PTOB may determine that the Provider's approval status be reevaluated.

D.5.0 PTOB's Annual Report on Provider Accreditation Status

The PTOB shall submit an annual report to NELAP and all AA's regarding the current accreditation status of PT Providers. NELAP may request additional information regarding a Provider including but not limited to: the PT Provider's monitoring data as described in Section D.4, final inspection reports and Provider responses, Initial

Application Forms, the frequency and results of studies and complaints received regarding a Provider.

D.6.0 DEVELOPMENT AND MAINTENANCE OF A COMPREHENSIVE PT DATABASE

A comprehensive PT database will be developed and maintained by the PTOB in conjunction with NELAC.

D.7.0 COMPLAINTS AND CORRECTIVE ACTION

The PTOB shall evaluate all complaints that it receives regarding either approved or candidate PT Providers. If the PTOB determines that a complaint warrants investigation, the PTOB shall notify the Provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTOB within thirty (30) days from the date the PTOB notifies the Provider. The PTOB shall provide to NELAP a summary of all PT Provider complaints received the previous year.

D.8.0 LIST OF APPROVED PT PROVIDERS

The PTOB shall maintain a list of approved PT Providers. The list shall be maintained on a continuing basis on an electronic bulletin board or similar means and will be readily available to laboratories seeking NELAC accreditation, state accrediting authorities and other interested parties. PT Providers must agree to abide by the provisions of NELAC regarding the advertising and marketing use of the designation, “PTOB Approved Proficiency Test Provider”.

D.9.0 SPONSORSHIP OF ANNUAL *NELAC PROFICIENCY TESTING CAUCUS*

The PTOB shall, in conjunction with NELAC, sponsor an annual *NELAC Proficiency Testing Caucus*. The *Caucus* shall, if possible, be held in conjunction with the annual NELAC meeting. The purpose of the *Caucus* is to provide a forum for PT Providers, Accrediting Authorities, laboratories, federal agencies, and other interested parties to exchange information regarding the PT study results of the previous year. The *Caucus* shall include technical presentations and open discussions on means to improve the Proficiency Testing aspect of NELAC with a continuing goal of improving the

quality of environmental data generated by the NELAC accredited laboratories.

D.10.0 PTOB ETHICS

This section describes the overall ethics and standards of conduct that must be adhered to in order for the PTOB to implement and administer a successful PT Provider oversight program. The PTOB shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding Providers' approval status. The PTOB shall be able to certify to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of Appendix D. The PTOB shall remain unbiased in evaluating information gathered and received including inspection reports, referee sample results, complaints, and any other information obtained regarding a PT Provider. The PTOB shall evaluate all information gathered and received about a Provider related to providing NELAC PT samples, and determine which information is relevant to the approval status of a Provider, and provide that information to NELAP, the AAs, the laboratories, and the public as appropriate.

D.11.0 CONFIDENTIALITY

A portion of the information provided to the PTOB by the PT Provider in the course of its inspection and oversight activities will be proprietary in nature. The PTOB will agree to maintain the confidentiality of proprietary information provided to it by the PT provider.